CLAIMS

1. A method for determining when an agent should be administered to a patient suffering from a disease characterized by the production of regulator cells, the method comprising monitoring the patient, or samples obtained therefrom, for at least one of: a) effector cell numbers and/or activity, b) regulator cell numbers and/or activity, c) a molecule associated with the disease, and/or d) an immune system marker.

2. A method of treating a disease characterized by the production of regulator cells, the method comprising;

i) monitoring a patient suffering from the disease for at least one of:

a) number and/or activity of regulator cells,

b) number and/or activity of effector cells,

c) a molecule associated with the disease, and/or

d) an immune system marker, and

ii) exposing the patient to an agent to treat the disease,

wherein the timing of administration of the agent is selected such that the activity of effector cells is not significantly reduced.

3. The method of claim 1 or claim 2, wherein the disease characterized by the production of regulator cells is cancer or an infection.

4. The method of claim 3, wherein the infection is a chronic persistent infection characterized by the patient s immune system not being able to eliminate the infection.

5. The method of claim 4, wherein the patient is infected with HIV, Hepatitis B virus or Hepatitis C virus.

6. The method according to any one of claims 1 to 5, wherein the immune system marker reflects the number and/or activity of regulator cells, and/or the number and/or activity of effector cells.

7. The method according to any one of claims 1 to 5, wherein the immune system marker is an acute phase inflammatory marker.

8. The method of claim 7, wherein the acute phase inflammatory marker is selected from the group consisting of: serum amyloid A, serum amyloid P and c-reactive protein.

9. The method according to any one of claims 2 to 5, wherein the agent is administered between when the levels of an acute phase inflammatory marker have peaked and before the marker begins to rise in the next cycle.

10. The method according to any one of claims 1 to 9, wherein the regulator cells are CD4+CD8- T cells.

11. The method according to any one of claims 2 to 5, wherein the agent is administered about when CD4+CD8- T cells are detected.

12. The method according to any one of claims 1 to 11, wherein the effector cells are CD8+CD4- T cells.

13. The method according to any one of claims 2 to 5, wherein the agent is administered approximately when CD8+CD4- T cell numbers have peaked.

14. The method according to any one of claims 1 to 13, wherein the molecule associated with the disease is an antigen produced by a cancer cell or an infectious agent.

15. The method according to any one of claims 2 to 5, wherein the agent is administered approximately when levels of the molecule associated with the disease begin to decrease.

16. The method according to any one of claims 1 to 5, wherein the patient is monitored for an acute phase inflammatory marker, and a molecule associated with the disease.

17. The method according to any one of claims 2 to 5 or 16, wherein the agent is administered between when the levels of the acute phase inflammatory marker have peaked and before the marker begins to rise in the next cycle, and when levels of the

molecule associated with the disease begin to decrease or would have been predicted to begin to decrease based upon previous analysis of the molecule.

18. The method according to any one of claims 1 to 17, wherein the patient is monitored for a period of at least 7 days.

19. The method according to any one of claims 1 to 18, the patient is monitored at least about every 3 days.

20. The method according to any one of claims 1 to 19, wherein the agent inhibits the production of, limits the function of, and/or destroys, regulator cells.

21. The method of claim 20, wherein the agent is selected from the group consisting of anti-proliferative drugs, radiation, dsRNA and antibodies which inhibit the production and/or activity of regulator cells.

22. The method of claim 21, wherein the anti-proliferative drug is selected from the group consisting of: taxol, vincristine, vinblastine and anhydro vinblastine.

23. The method of claim 21, wherein the antibody is selected from the group consisting of: anti-CD4+, anti-CTLA-4 (cytotoxic lymphocyte-associated antigen-4), anti-GITR (glucocorticoid-induced tumour necrosis factor receptor), anti-CD28 and anti-CD25.

24. The method according to any one of claims 1 to 23, wherein the patient has not been exposed to a treatment for the disease for at least 14 days.

25. The method according to any one of claims 1 to 24, wherein the patient is a human.

26. A method of diagnosing a disease characterized by the production of regulator cells, the method comprising monitoring the patient, or samples obtained therefrom, for at least one of: a) effector cell numbers and/or activity, b) regulator cell numbers and/or activity, c) a molecule associated with the disease, and/or d) an immune system marker, wherein cycling of any one of a) to d) indicates the disease may be present.

27. A method for determining when a vaccine should be administered to a patient suffering from a disease characterized by the production of regulator cells, the method comprising monitoring the patient, or samples obtained therefrom, for at least one of: a) effector cell numbers and/or activity, b) regulator cell numbers and/or activity, c) a molecule associated with the disease, and/or d) an immune system marker.

28. A method of treating a disease characterized by the production of regulator cells, the method comprising;

i) monitoring a patient suffering from the disease for at least one of:

a) number and/or activity of regulator cells,

b) number and/or activity of effector cells,

c) a molecule associated with the disease, and/or

d) an immune system marker, and

ii) exposing the patient to an vaccine to treat the disease,

wherein the timing of administration of the vaccine is selected such that the activity of effector cells is not significantly reduced.

29. The method of claim 28, wherein the vaccine is administered about when the levels of effector cells are increasing.

30. The method of claim 28, wherein the vaccine is administered about when the levels of a molecule associated with the disease begin to decrease.

31. The method of claim 28, wherein the vaccine is administered about when the levels of an acute phase inflammatory marker begin to increase.

32. Use of an assay which detects an immune system marker for determining when an agent or vaccine should be administered to a patient suffering from a disease characterized by the production of regulator cells.

33. The use of claim 32, wherein the marker is an acute phase inflammatory marker.

34. The use of claim 33, wherein the acute phase inflammatory marker is selected from the group consisting of: serum amyloid A, serum amyloid P and c-reactive protein.

35. Use of an assay which detects effector cell numbers and/or activity for determining when an agent or vaccine should be administered to a patient suffering from a disease characterized by the production of regulator cells.

36. The use of claim 35, wherein the assay detects the number of CD8+CD4- T cells.

37. Use of an assay which detects regulator cell numbers and/or activity for determining when an agent or vaccine should be administered to a patient suffering from a disease characterized by the production of regulator cells.

38. The use of claim 37, wherein the assay detects the number of CD4+CD8- T cells.

39. Use of an assay which detects a molecule associated with a disease characterized by the production of regulator cells for determining when an agent or vaccine should be administered to treat the disease.

40. The use of claim 39, wherein the assay detects an antigen produced by a cancer cell or an infectious agent.

41. The use according to any one of claims 32 to 40, wherein a patient with the disease has not been exposed to a treatment for the disease for at least 14 days.

42. Use of an agent for the manufacture of a medicament for administering to a patient suffering from a disease characterized by the production of regulator cells, wherein the agent will be administered at a time selected such that the activity of effector cells is not significantly reduced, and wherein the patient has not been exposed to a treatment for the disease for at least 14 days.

43. The use according to any one of claims 32 to 42, wherein the agent inhibits the production of, limits the function of, and/or destroys, regulator cells.

44. A kit for determining when an agent or vaccine should be administered to a patient suffering from a disease characterized by the production of regulator cells, the kit comprising at least one reagent for monitoring the patient, or samples obtained

therefrom, for at least one of: a) effector cell numbers and/or activity, b) regulator cell numbers and/or activity, c) a molecule associated with the disease, and/or d) an immune system marker.